

SCF (SEQ ID NO:1) resembles the others less than they resemble one another (**Table III**). The comparison in this study of SCF with other short-chain helical cytokine structures [granulocyte-macrophage colony-stimulating factor (GM-CSF) Diederichs et al., 1991), M-CSF (Pandit et al., 1992), and IL-5 (Milburn et al., 1993)] shows greatest structural similarity with M-CSF (SEQ ID NO:2) or IL-4 (SEQ ID NO:3), but even here fewer than half of the residues can be superimposed (**Table III**). Sequence similarities are essentially random. A structure-based sequence alignment (**Figure 3**) of SCF with other short-chain helical cytokines has pairwise identities ranging from 6.7% to 18.8% (**Table III**) and not even a single residue in SCF is conserved in all the others. Moreover, the best alignment presented in Figure 3 is only valid for the specified criteria herein, and it differs somewhat from that given by Rozwarski et al. (Rozwarski et al., 1994). Indeed, because of variability in the core structures in this divergent superfamily, a self-consistent pairwise alignment of the family members has not been able to be achieved. Nevertheless, the core elements are remarkably similar in structure.--

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REMARKS

The August 2, 2001 Office Communication stated that the above-identified application failed to comply with 37 C.F.R. §1.821-1.825 as there are sequences in the figures that are not assigned sequence identifiers, and the sequences within the C.R.F. submitted with the application are not described in the specification as to what they relate to. Applicants attach hereto a copy of the Communication as **Exhibit A**. In response applicants have amended the figure descriptions and written description to comply with 37

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C.F.R. §1.821. A marked-up copy of the amendments to the figure description and written description is enclosed as **Exhibit B**. The amendments clarify which sequences in the CRF submitted with the application correspond to which sequences in the specification. The amendments merely insert sequence ID numbers into the specification. Applicants maintain that the amendments to the figure description and written description raise no issue of new matter. Accordingly, applicants respectfully request that this Amendment be entered.

Species Election

In the August 2, 2001 Office Communication, the Examiner to whom the subject application is assigned stated that a Species Election is required for the purposes of examination. This election is further to the previous election of group IV claims submitted June 1, 2001 in response to a May 7, 2001 Office Action issued in connection with the above-identified application.

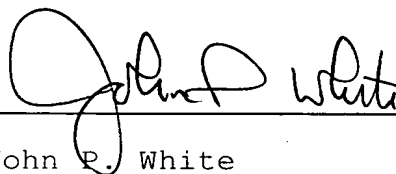
In response to this species election requirement, applicants hereby elect, with traverse, the SEQ ID NO:1 for the purposes of examination.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invite the Examiner to telephone him at the number provided below.

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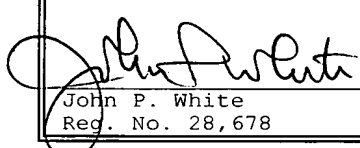
No fee, apart from the enclosed fee of \$110.00 for a one-month extension of time, is deemed necessary in connection with the filing of this Communication. If any other fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Attorney for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.



John P. White
Reg. No. 28,678

10/2/01
Date

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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

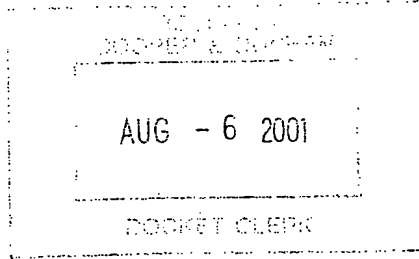
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Washington, D.C. 20231

JPW

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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m. 9.2.01
m. 10.2.01
m. 11.2.01
n. 12.2.01
n. 1.2.02
n. 2.2.02

AP



EXAMINER

ART UNIT	PAPER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Non-Compliance with Sequence Compliance Rules.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821 (a) (1) and (a) (2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because there is a lack of sequence identifiers (SEQ ID NO: X). It is noted that sequences which fall under the above sequence rules are present in the Figures. In such situations the SEQ ID NOs are not required in the Figures per se, but rather the SEQ ID NOs for the sequences in each Figure may be amended into the Brief Description of the Figures section in the specification. In addition, please include sequence identifiers within the specification where needed. The sequences within the CFR are not described within the specification as to what they correlate to, and thus can not be properly examined. Please provide a description of the sequences submitted. Applicant is required to complete the response within a time limit of one month from the date of this letter or as extended as follows. AN EXTENSION OF THIS TIME LIMIT MAY BE GRANTED UNDER EITHER 37 CFR § 1.136 (a) OR (b) UP TO A MAXIMUM OF SIX MONTHS.

Species Election:

It is noted that the CRF provided contains more than one sequence. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each of the groups of the Restriction Election, Paper No. 8, 7 May 2001. For an elected Group drawn to amino acid sequences, the Applicant(s) must further elect a single amino acid sequence. The Applicant elected group IV, a method for designing a compound concerning the use of a polypeptide sequence.

It has been determined that 1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of 1 (one) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

Examination will be restricted to only the elected sequence.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

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Exhibit A

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 8 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 23, 2001
Monika B. Sheinberg

MBS

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.



UNITED STATES DEPARTMENT OF COMMERCE

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07/055,482	08/29/00	HENDRICKSON	W 50550/JFW/EN

JOHN P. WHITE, ESQ.
COOPER & DUNHAM LLP
1185 AVENUE OF THE AMERICAS
NEW YORK NY 10036

HM12/0802

EXAMINER

SHEINBERG, M

ART UNIT

1531

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DATE MAILED:

08/02/01

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Commissioner of Patents and Trademarks

Marked-up Version Of Amendments

Additions to the text are indicated by underlining; deletions are indicated by square brackets.

The figure description starting at page 12, line 20 has been amended as follows:

--Figure 3.

Structure-based sequence alignment of SCF (SEO ID NO:1) with other short-chain helical cytokines of human species. The dots denote gaps. M-CSF (SEO ID NO:2), IL-4 (SEO ID NO:3), GM-CSF (SEO ID NO:4), IL-2 (SEO ID NO:5) and IL-5 (SEO ID NO:6) were aligned with SCF structure through structural superposition using TOSS (Hendrickson, 1979) and O (Jones et al., 1991). C α atoms were included if within 3.0 Å of their counterparts after superposition and at least three consecutive such residues are found in the fragment. The secondary structure elements were assigned according to the output of the PROCHECK program (Laskowski et al., 1993) except the helix assignment for residues 35-38, which was identified by inspection of the hydrogen-bond pattern. Secondary structures are shown shaded [in yellow] with filled boxes referring to α -helices, half-filled boxes to 3_{10} -helices and arrows to β -strands. The solvent accessibility of the SCF dimer is indicated for each residue by an

open circle if the fractional solvent accessibility is >0.4 , a half-filled circle if it is $0.1-0.4$, and a filled circle if it is <0.1 . Residues at the SCF dimer interface are identified by stars, and the N-linked glycosylation sites by [red] Ys above the Asn residues.--

The figure description starting page 14, line 5 has been amended as follows:

--Figure 5. Sequence alignment of SCF from human (SEO ID NO:7), mouse (SEO ID NO:8), rat (SEO ID NO:9) and dog (SEO ID NO:10). (Anderson et al., 1990; Huang et al., 1990; Martin et al. 1990; Shull et al., 1992) The residues that are conserved in human and dog but different from rat and mouse are shadowed [in yellow]. Five regions of divergent sequence are identified (Roman numerals) Dots denote gaps, and dashes indicate residues identical to the human residues.--

The paragraph beginning page 62, line 3 has been amended as follows:

--Although SCF has the characteristic features of short-chain helical cytokines, as among other members, both sequence and structure are highly divergent. If anything, SCF (SEO ID NO:1) resembles the others less than they resemble one another (**Table III**). The comparison in this

study of SCF with other short-chain helical cytokine structures [granulocyte-macrophage colony-stimulating factor (GM-CSF) Diederichs et al., 1991), M-CSF (Pandit et al., 1992), and IL-5 (Milburn et al., 1993)] shows greatest structural similarity with M-CSF (SEQ ID NO:2) or IL-4 (SEQ ID NO:3), but even here fewer than half of the residues can be superimposed (**Table III**). Sequence similarities are essentially random. A structure-based sequence alignment (**Figure 3**) of SCF with other short-chain helical cytokines has pairwise identities ranging from 6.7% to 18.8% (**Table III**) and not even a single residue in SCF is conserved in all the others. Moreover, the best alignment presented in Figure 3 is only valid for the specified criteria herein, and it differs somewhat from that given by Rozwarski et al. (Rozwarski et al., 1994). Indeed, because of variability in the core structures in this divergent superfamily, a self-consistent pairwise alignment of the family members has not been able to be achieved. Nevertheless, the core elements are remarkably similar in structure.--